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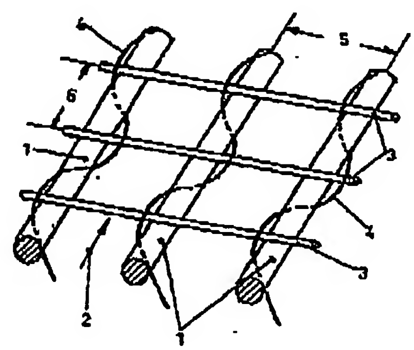
54 Dialyzer composed of stacked semipermeable tubing sections

57 In a dialyzer with a housing and, disposed thereon, supply lines and discharge lines for blood and dialyzate, stacked semipermeable tubing sections are disposed in the housing and each have in their interior a membrane holder composed of unwoven synthetic material of intersecting threads. The flow path for the dialyzate is formed in the tubing sections, and the flow path for the blood is formed between the tubing sections crosswise thereto. In order to show a dialyzer which in conjunction with efficiently degassing and also with poorly degassing dialysis machines exhibits about the same pressure drop and shows optimal properties with a minimal blood film thickness, the membrane holder is formed in the flow direction of the dialyzate through the use of comparatively thick warp threads at a mutual distance a plurality of unimpeded dialyzate pathways. The membrane holder has in the flow direction of the blood, through the use of weft threads which are thinner by comparison therewith, a plurality of unimpeded blood pathways of low film thickness at a mutual distance.



Dialyzer composed of stacked semipermeable tubing sections

The invention relates to a dialyzer with a housing and, dispersed thereon, supply lines and discharge lines for blood and dialyzate and with stacked semipermeable tubing sections disposed in the housing, each of which have in their interior a membrane holder composed of unwoven synthetic material of intersecting threads which forms the flow path for the dialyzate in the tubing sections and forms the flow path for the blood between the tubing sections crosswise thereto.

Dialyzers of this type are disclosed in DE-OS 20 24 635. The membrane holder which is disposed in each tubing section consists of unwoven material which is as thin as possible, that is to say of synthetic threads which are superimposed crosswise and are stabilized on each other by the action of heat. Threads have approximately the same diameter, irrespective of the direction in which they are inserted. Inasmuch as the dialyzate is conveyed in the interior of the tubing sections and past the membrane holders, the membrane holder represents a considerable impediment on which, especially in conjunction with poorly degassing machines, gas bubbles separate out and lead to an increase in the resistance and thus to a pressure drop on the dialyzate side. In conjunction with efficiently degassing machines, there is scarcely any such pressure drop on the dialyzate side. Hence the disadvantageous consequence is that the dialyzer has apparently different properties depending on the machine with which it is employed in conjunction. This interferes with the operation of a machine and of a dialyzer, quite apart from the fact that in some circumstances the intended dehydration of the patient is not achieved by ultrafiltration in conjunction with a poorly degassing machine.

The same disadvantage is also observed with the Hoeltzenbein crossed-channel dialyzer. This is not at all surprising since, after all, the parallel channels elicit very similar properties as does the use of an unwoven membrane holder using parallel threads. This may lead to the occurrence of a pressure drop, if the separation out of gas in the crossed-channel dialyzer is appropriately large, such that the machine employed in this case switches off, as a result of the safety devices provided thereon, and thus interrupts the dialysis process.

Every dialyzer, with a coil, capillary or plate, acts in the dialyzate part like a gas separator. Smaller dialyzate pathways mean greater separation out of gas. Large gas bubbles are generated for example by plate-type dialyzers. If these bubbles remain suspended in the membrane holders, the membrane area over which there is no flow, due to the bubbles, is no longer available for diffusion. With small or medium-sized bubbles, the diffusion pathways are too long. In both cases, the total clearance is reduced.

In the dialyzer disclosed in DE-OS 27 54 220, a special fabric whose interstices have a

side length of 0.3 mm is used as membrane holder. This achieves inter alia dispersion of the otherwise usual large gas bubbles into very small bubbles with a maximum radius of 0.15 mm. These bubbles occupy the apertures of the fabric. In the operating state, the dialyzate flows round these gas bubbles. The diffusion distance accordingly amounts to a maximum of only 0.15 mm. The diffusion is therefore maintained even when the dialyzate part is filled with gas. This mode of action can be demonstrated by comparing the clearances of a non-degassing dialysis machine with that of an efficiently degassing dialysis machine. The difference which appears is attributable to the smaller amount of dialyzate per minute in the non-degassing machine. Gas-filled dialyzate parts thus have no influence on the clearance in this known dialyzer. However, on use of poorly degassing machines it is necessary to take account of some matters related to measurement methods when measuring and adjusting the ultrafiltration, which matters make application difficult. The gas bubbles act as flow resistance to the dialyzate. If the degassing of the dialyzate is poor, the bubbles fill up the unoccupied apertures of the fabric within 15 to 30 minutes. This resistance may rise to about 160 mm Hg. A stationary state is reached after 30 minutes, i.e. all the unoccupied apertures in the fabric are filled with gas. Gas which has newly separated out is now completely discharged.

Even with very efficiently degassing machines, a few gas bubbles are to be observed, specifically with a high transmembrane pressure, that is to say high pressure difference across the membrane. Possibilities here are, as a result of the great permeability of the membrane, diffused CO_2 from the blood or else "air leaking" in the dialyzate coupling. An increase in the flow resistance will in this case not occur in this order of magnitude. The increased flow resistance in poorly degassing machines has an effect on the measurement and adjustment of the ultrafiltration rate of the dialyzer, specifically depending on how and where the transmembrane pressure is measured. The measurement of the ultrafiltration rate customary in practice cannot encompass such situations because it takes no account either of the location of the pressure measurement or of the flow resistance. Since, for example, only the pressures occurring at the blood and dialyzate outlet sides are taken into account, and apparent transmembrane pressure results and differs more or less, depending on the conditions, from the actual transmembrane pressure. For a more accurate determination of the ultrafiltration rate it is necessary to measure the pressure on the blood and dialyzate inlet sides and outlet sides. Averaging results in a transmembrane pressure which comes very close to the actual conditions. However, since in most dialysis machines no pressure measurement is provided in the blood pathway and in the dialyzate pathway on the inlet side and outlet side and, on the contrary, measurement at the outlet side is usually regarded as sufficient, the ultrafiltration rate can be determined only on the basis of the apparent transmembrane pressure, so that it is associated with a great uncertainty which depends on how efficient or how poor the degassing of the relevant dialysis machine is. For example, on use of a poorly degassing machine and with low dehydration of the patient, it will be advisable to adjust a pressure which is

correspondingly low. It is possible in such cases for the ratio of the apparent transmembrane pressure to the actual transmembrane pressure to be 2:3.

The invention is therefore based on the object of producing a dialyzer of the type described at the outset with a membrane support for thin dialyzate films which has a minimal pressure drop on the dialyzate side when gas separates out of the dialyzate. In other words, the intention is to design the dialyzer so that, irrespective of whether it is employed in conjunction with an efficiently degassing or with a poorly degassing dialysis machine, the pressure drop changes within relatively narrow limits, that is to say is so small that it shows variations which are not unacceptable for the ultrafiltration rate.

This is achieved according to the invention by the membrane holder having, in the direction of flow of the dialyzate, through the use of comparatively thick warp threads at a distance, a plurality of unimpeded dialyzate pathways, and by the membrane holder having, in the direction of flow of the blood through the use of comparatively thin weft threads at a distance a plurality of thin flow paths for the blood, and by the weft threads being stabilized on the warp threads. The invention is based on taking account of the different properties of the blood on the one hand and of the dialyzate on the other hand, also in relation to the configuration of the membrane holder, and on providing the dialyzate with a substantially unimpeded pathway so that gas bubbles are scarcely able to become established and thus a pressure drop scarcely occurs in conjunction with poorly degassing machines. In contrast to the use of a crossed-channel lattice or of a corresponding fabric as membrane holder, in which each dialysis path is formed by a large plurality of individual chambers which may each be filled with one gas bubble, in this case at best only one gas bubble is now disposed in a dialyzate pathway in each case. As a result thereof, the capillary forces to be overcome in the dialyzate pathway in the design according to the invention are very much lower. On the other hand, it is necessary to minimize the blood film thickness, that is to say to provide the blood with a plurality of thin flow paths which, in terms of their magnitude, are also sufficiently stable over a prolonged period. Such a design according to the invention of the membrane holder achieves the advantage that the dialyzer itself can have very small dimensions and a low weight, but on the other hand a relatively large membrane area is accommodated in a very small space. This is desirable and advantageous in many respects, for example it results in a small blood capacity. Accordingly, in turn there is no problem with returning blood with small amounts of rinsing liquid at the end of the dialysis. However, above all, there is no great change in the transmembrane pressure - irrespective of whether the dialyzer is employed in conjunction with a poorly or efficiently degassing dialysis machine. Linear control of the ultrafiltration is thus possible over a long period and large range. It is self-evident that the membrane holder, which is configured differently in relation to its warp threads and weft threads, will then also be disposed in the predetermined alignment within the semipermeable tubing sections.

The warp threads and weft threads can be provided with geometric dimensions such that the tubing sections sag as little as possible, and thus a flow path with an average thickness of about 50 μ is formed. A thin blood film is thus exposed on the membrane surface, so that the diffusion pathways are comparatively short.

The warp threads substantially determine the stability of the membrane holder, with the stabilization of the weft threads on the warp threads being brought about by a bonding and/or a loop formation with use of a thin loop thread. This loop thread is so thin that it does not impede the unimpeded dialyzate pathways and also has no adverse effect on the blood film thickness. The warp threads forming the unimpeded dialyzate pathways have a diameter which, on the one hand, is sufficiently large for discharge of gas which has separated out and, on the other hand, is sufficiently small to form thin dialyzate films. Optimization of these two opposing requirements can be achieved by taking account of the physical limits. In this connection, the warp threads can have a diameter of between 0.15 to 0.3 mm - preferably 0.2 mm -, a mutual distance of between 0.5 mm to 1.0 mm - preferably 0.6 mm -, the weft threads can have a diameter of 0.08 mm to 0.15 mm - preferably 0.12 mm - and a mutual distance of 1.0 to 2.0 mm - preferably 1.2 to 1.6 mm. The stated ranges are beneficial for preventing all too great a range of alteration in the transmembrane pressure. If, for example, the warp thread is chosen to be too thick, that is to say for example thicker than 0.3 mm, this leads to a restriction of the dialysis efficiency. If the distance of the weft threads is chosen to be too large, then the membrane between them sags too much, so that the average blood film thickness is increased in a disadvantageous manner.

In the case of stabilization of the weft thread on the warp thread by a loop thread, the latter can have a diameter of about 0.08 mm, so that it is negligible in relation to the warp threads and weft threads, but on the other hand forms a good technical possibility for stabilizing the weft threads on the warp threads. The warp threads can consist of polyethylene, the weft threads can consist of polyester or polyacrylic and the loop threads can consist of polyamide.

It is also possible not only to dispose in each case one weft thread at a distance from the adjacent weft thread on the warp thread, but also in each case two weft threads directly adjacently on single warp threads which are disposed at a distance, and then to stabilize these weft thread pairs again at a distance from one another. This manufacture-related implementation has proved to be very worthwhile.

It is possible advantageously on use of a loop thread to dispose at least two different types of membrane holders, which differ in that they have in each case a different distance from adjacent weft threads, alternatingly in the stack. In this way, the ordered sliding of membrane holders into adjacent membrane holders, and thus uncontrolled alteration of the height of the stack, is avoided. If the two distances are set up on a

common dividing grid, and in each case amount to a different whole-line multiple of the dividing grid, the result is a precise supporting of two adjacent membrane holders at regularly recurring distances throughout the adjoining membranes, in particular irrespective of the relative displacement position in which the two membrane holders are mutually located. This summed over the entire height of the stack results in a reliable reproducible supporting of the individual membrane holders on each other, a reproducible height of the stack, reproducible thin blood film pathways and a good distribution of the blood into the individual blood film pathways. There are manufacturing advantages also in relation to the disposition of the sealing of the membrane stack.

The invention is further explained and described on the basis of some exemplary embodiments. Shown in

Fig. 1 is a detail of a perspective representation of the membrane holder in a first embodiment,

Fig. 2 is a detail of a perspective representation of the membrane holder in a second embodiment,

Fig. 3 is a cross section through a part of the membrane stack of a third embodiment along line III-III in Fig. 4 and

Fig. 4 is a section through the embodiment shown in Fig. 3 along line IV-IV.

The construction of the dialyzer substantially corresponds to that shown in DE-OS 27 54 220 and is thus assumed to be known. In this case, a plurality of semipermeable tubing sections are arranged in a stack, with a membrane holder composed of unwoven synthetic material of intersecting threads being provided in each case in the interior of each tubing section. Such a membrane holder is shown in detail and in greatly magnified representation in Fig. 1. The membrane holder consists of comparatively thick warp threads 1 which are disposed at a distance from one another and extend in the direction of flow 2 of the dialyzate. The axis of each tubing section also extends in this direction. Perpendicular thereto, comparatively thinner weft threads 3 are placed at equal distances on the warp threads 1 and stabilized with the aid of one loop thread 4 in each case. As can be seen, the loop thread 4 has a very small diameter. The warp threads 1 consist of polyethylene and have for example a diameter of 0.2 mm and a mutual distance 5 of 0.6 mm. The weft threads 3 consist of polyester and have a diameter of 0.12 mm and a mutual distance 6 of 1.5 mm. The loop thread 4 consists of polyamide and has a diameter of 0.08 mm. The warp threads 1 substantially determine the stability of the membrane holder. The weft threads 3 which are stabilized thereon serve substantially for membrane bearing on one side, whereas on the other side the membrane lies on the underside of the warp threads 1.

Fig. 2 shows a similar configuration in which, however, two weft threads 3 are in each case disposed directly adjacent to one another, and the distance 6 between two adjacent pairs of weft threads is maintained. The use of a loop thread 4 for stabilization is dispensed with here. Instead, the synthetic threads are fixed to one another or stabilized by a thermal treatment. Here too, the warp threads 1 extend in the direction of flow 2 of the dialyzate, while the weft threads 3 are disposed in the direction of flow 7 of the blood.

Figs. 3 and 4 show an embodiment depicted in cross section which emerges on combination of the embodiments shown in Figs. 1 and 2, namely the use of in each case two weft threads 3 directly adjacent to one another and by stabilization with the aid of a loop thread 4. In each case, three layers are depicted one on top of the other so that they result in a stack. Fig. 3 shows a section through the weft threads 3 so that the warp threads 1 run horizontally in the plane of the drawing. Each of the three membrane holders is surrounded by a tubular membrane 8, so that a flow path 9 for the blood film in the direction of flow 7 is formed between two membranes. The dialyzate flows in the region of the membrane holder perpendicular to the plane of the drawing. Fig. 3 illustrates the small average thickness of the flow paths 9 for the blood, which is approximately of the order of 50 μ.

In the stacks shown in Fig. 3, two different types of membrane holders are employed and are disposed alternatingly in each case. The top and bottom membrane holder is of the same type, while the middle membrane holder differs therefrom. This difference consists of the fact that the weft thread pairs 3 have an equal distance 6 from one another which is chosen to be comparatively large from one another, whereas the middle layer has a comparatively smaller distance 6'. The distance 6 may be for example 1.5 mm and the distance 6' for example 1.25 mm. The loop thread 4 when it loops round the weft thread 3 projects beyond the latter with its part 10 upwards, whereas it projects downwards in each case with its part 11 at the point of looping round the weft thread 1. The different configuration of the distances 6 and 6' and the alternating disposition of these two types of membrane holders result in displacement of the point of overlap of parts 10 and 11 of the loop thread 4 of adjacent membranes relative to one another in each case. The result at comparatively larger distances is that part 11 of the loop thread is supported on a part 10 of an adjacent loop thread, as is the case at point 12. These points 12 are repeated at regular distances transversely through the stack, that is to say along the direction of the arrow 7. In this way, support points 12 are formed and guarantee a reproducible distance between adjacent membranes and thus also a reproducible stack height of the membranes in the dialyzer, in particular irrespective of whether and how far the membranes are displaced in their random layer relative to one another (in the direction of the arrows 7). A further support point 13 is depicted between the middle layer and the lower layer. If a membrane holder is displaced relatively in the direction of the arrows 7, the support

point 12 or 13 merely changes its location without the distance between the two layers being altered thereby.

The unimpeded dialyzate pathways 14 are very clearly evident from the depiction in Fig. 4, that is to say a section at 90° relative to Fig. 3. The direction of flow 2 of the dialyzate in this case extends perpendicular to the plane of the drawing. It is seen how the warp threads 1 of adjacent membrane holders appear irregularly offset relative to one another, and the flow path 9 extends in each case transversely in the direction of the arrows 7.

Claims:

1. Dialyzer with a housing and, dispersed thereon, supply lines and discharge lines for blood and dialyzate and with stacked semipermeable tubing sections disposed in the housing, each of which have in their interior a membrane holder composed of unwoven synthetic material of intersecting threads which forms the flow path for the dialyzate in the tubing sections and forms the flow path for the blood between the tubing sections crosswise thereto characterized in that the membrane holder has, in the direction of flow (2) of the dialyzate, through the use of comparatively thick warp threads (1) at a distance (5) a plurality of unimpeded dialyzate pathways (14), and in that the membrane holder has, in the direction of flow (7) of the blood through the use of comparatively thin weft threads (3) at a distance (6) a plurality of thin flow paths (9) for the blood, and in that the weft threads (3) are stabilized on the warp threads (1).

2. Dialyzer according to Claim 1, characterized in that the warp threads and weft threads (1, 3) are provided with geometric dimensions such that the tubing sections sag as little as possible, and thus a flow path (9) with an average thickness of about 50° is formed.

3. Dialyzer according to either of Claims 1 or 2, characterized in that the warp threads(1) substantially determine the stability of the membrane holder, and in that the stabilization of the weft threads (3) on the warp threads (1) is brought about by a bonding and/or a loop formation with use of a thin loop thread (4).

4. Dialyzer according to Claim 1, characterized in that the warp threads (1) forming the unimpeded dialyzate pathways (14) have a diameter which, on the one hand, is sufficiently large for discharge of gase which has separated out and, on the other hand, is sufficiently small to form thin dialyzate films.

5. Dialyzer according to any of Claims 1 to 4, characterized in that the warp threads (1) have a diameter of between 0.15 to 0.3 mm - preferably 0.2 mm -, a mutual distance (5) of between 0.5 to 1.0 mm - preferably 0.6 mm -, the weft threads (3) have a diameter of 0.08 to 0.15 mm - preferably 0.12 mm - and a mutual distance (6) of 1.0 to 2.0 mm - preferably 1.2 to 1.6 mm.

6. Dialyzer according to any of Claims 1 to 4, characterized in that when the weft thread (3) is stabilized on the warp thread (1) by a loop thread (4) the latter has a diameter of about 0.08 mm.

7. Dialyzer according to any of Claims 1 to 6, characterized in that the warp thread (1) consists of polyethylene, the weft thread (3) of polyester or polyacrylic and the loop thread (4) of polyamide.

8. Dialyzer according to any of Claims 1 to 7, characterized in that in each case two weft threads (3) are stabilized directly adjacently on single warp threads (1) which are disposed at a distance, and these weft thread pairs are then stabilized again at a distance from one another.

9. Dialyzer according to any of Claims 1 to 8, characterized in that on use of a loop thread (4) at least two different types of membrane holders, which differ in that they have in each case a different distance (6, 6') from adjacent weft threads (3), are disposed alternatingly in the stack.

10. Dialyzer according to Claim 9, characterized in that the two distances (6, 6') are set up on a common dividing grid, and in each case amount to a different whole-part multiple of the dividing grid.

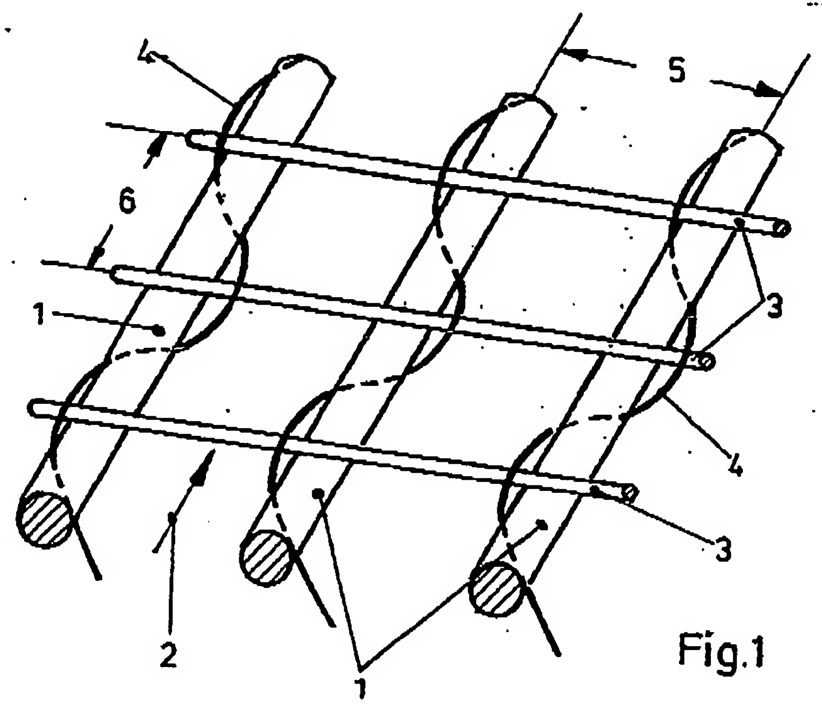


Fig.1

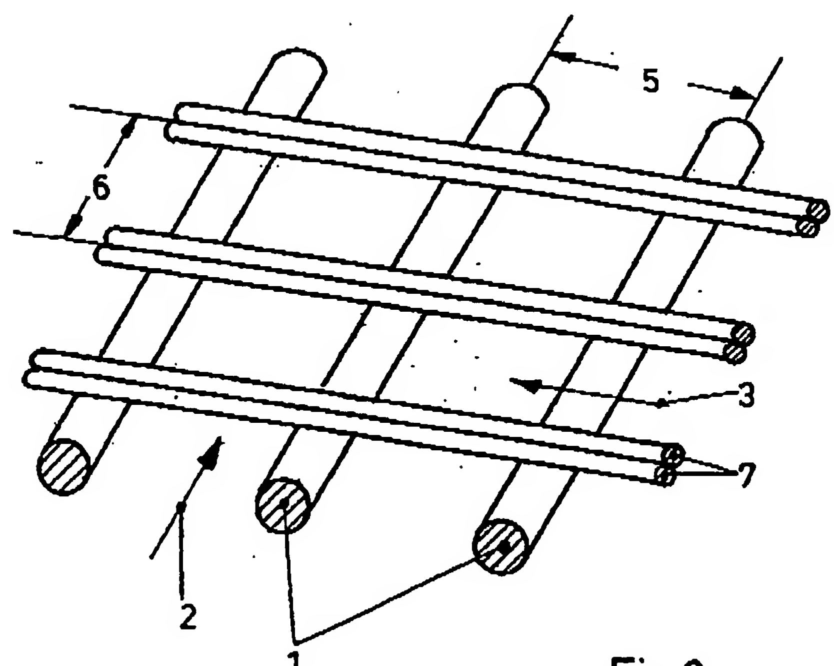


Fig.2

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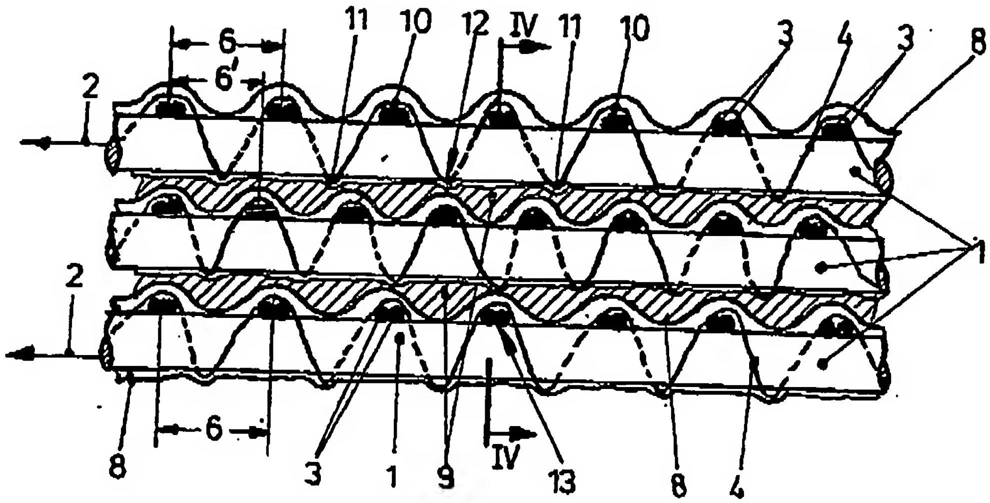

Fig.3

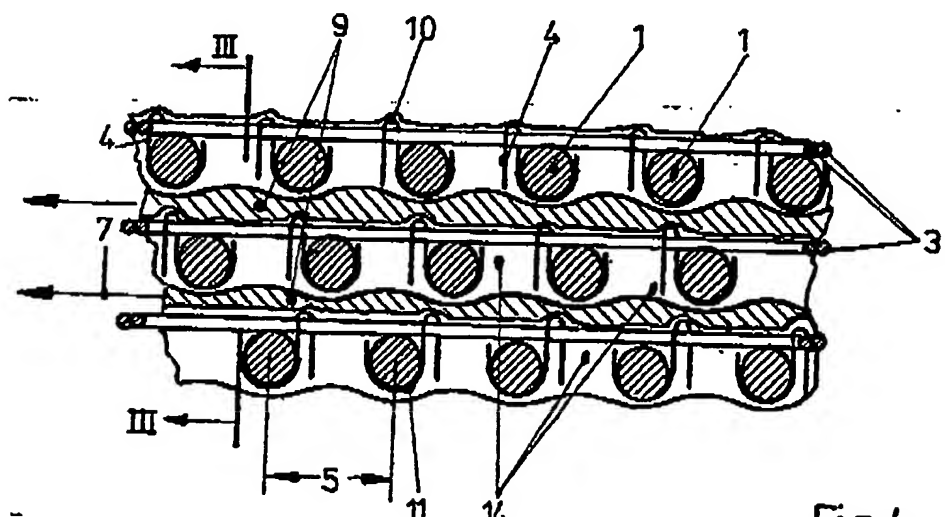

Fig.4